

tained less than 97 percent of the amount of ketosteroids necessary to produce a potency of 20,000 International Units of estrone per cubic centimeter, and some vials in one of the shipments of *Aqua-Gyne* contained less and some vials contained more than 97 percent of the amount of ketosteroids necessary to produce a potency of 20,000 International Units of estrone per cubic centimeter. The *Aqueous Estrogyne* possessed a potency of less than 20,000 International Units of estrone activity per cubic centimeter.

Misbranding, Section 502 (a), the *Aqua-Gyne* label statement "Each cc. * * * contains * * * (Ketosteroids as Estrone, approximately 97% by potency) * * * equivalent to 20,000 I. U. (assayed in terms of Estrone)" and the *Aqueous Estrogyne* label statement "1 cc. Aqueous Estrogyne 20,000 I. U. Estrone per cc." were false and misleading.

DISPOSITION: November 13, 1951. The corporation having entered a plea of guilty to the 8 counts of the information and the individual having entered a plea of guilty to the 6 counts of the information in which he was charged as a defendant, the court imposed a fine of \$800 against the corporation and suspended the imposition of sentence against the individual and placed him on probation for 1 day.

3572. Adulteration and misbranding of conjugated estrogens. U. S. v. 1 Drum
* * *. (F. D. C. No. 30965. Sample No. 19252-L.)

LIBEL FILED: June 27, 1951, District of Minnesota.

ALLEGED SHIPMENT: On or about April 12, 1951, by the Keith Victor Pharmaceutical Co., from St. Louis, Mo.

PRODUCT: 1 drum containing 23,850 tablets of *conjugated estrogens* at Minneapolis, Minn. Analysis showed that the product contained a total amount of estrogenic steroids calculated as 0.82 mg. of sodium estrone sulfate per tablet.

LABEL, IN PART: "Sugar Coated Estrogen 1.25 Mg. tablets each tablet contains naturally occurring water-soluble conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), the label statement "each tablet contains naturally occurring water-soluble conjugated Estrogens equivalent in biological activity to 1.25 Mg. of Sodium Estrone Sulfate" was false and misleading since the biological activity of the article was less than that declared.

DISPOSITION: September 5, 1951. Default decree of destruction.

3573. Adulteration and misbranding of conjugated estrogens. U. S. v. 3 Bottles
* * *. (F. D. C. No. 31220. Sample No. 813-L.)

LIBEL FILED: June 27, 1951, Southern District of Florida.

ALLEGED SHIPMENT: During or about December 1950, by the Robin Pharmacal Corp., from New York, N. Y.

PRODUCT: 3 1,000-tablet bottles of *conjugated estrogens* at Miami Beach, Fla. Analysis showed that the product contained a total amount of estrogenic steroids calculated to 0.59 milligram of sodium estrone sulfate per tablet.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 1.25 mg. of

estrogens in their naturally occurring water-soluble form, expressed as sodium estrone sulfate.

Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 mg. of estrogens in their naturally occurring water soluble form, expressed as sodium estrone sulfate" was false and misleading as applied to an article which contained less than the stated amount of estrogens.

DISPOSITION: August 17, 1951. Default decree of forfeiture and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3574. Misbranding of conjugated estrogens. U. S. v. 1 Bottle * * *. (F. D. C. No. 30960. Sample No. 13099-L.)

LIBEL FILED: June 30, 1951, Northern District of Texas.

ALLEGED SHIPMENT: On or about March 8, 1951, by the Spartan Pharmaceutical Co., from New York, N. Y.

PRODUCT: 1 1000-tablet bottle of *conjugated estrogens* at Lubbock, Tex.

LABEL, IN PART: "Spartan Conjugated Estrogens."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Each tablet contains 1.25 Mg. of Estrogens in their naturally occurring water soluble conjugated form expressed as Sodium Estrone Sulfate" was false and misleading as applied to an article which contained 0.78 mg. of total estrogenic steroids calculated as sodium estrone sulfate.

DISPOSITION: October 24, 1951. Default decree of condemnation and destruction.

3575. Misbranding of Dolcin. U. S. v. 164 Cartons * * *. (F. D. C. No. 27355. Sample No. 13531-K.)

LIBEL FILED: June 23, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about May 11, 1949, by the Dolcin Corp., from Buffalo, N. Y.

PRODUCT: 164 cartons, each containing 1 bottle, of *Dolcin*, a leaflet entitled "Dolcin," and a business reply card at Trenton, N. J. Analysis indicated that the product consisted essentially of aspirin, 2.6 grains, and calcium succinate, 3.4 grains.

LABEL, IN PART: (Bottle) "Dolcin For Relief of Symptoms Arthritis Rheumatism Dolcin Corporation, New York, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle and carton labels, on the business reply card, and in the leaflet were false and misleading. The statements represented and suggested that the article was adequate and effective for the treatment and cure of rheumatism and arthritis, whereas the article was not effective for such purposes.

DISPOSITION: October 2, 1951. The Dolcin Corp., claimant, having filed an answer denying that the product was misbranded and later having been permitted to withdraw its claim and answer with the understanding that such withdrawal should not be deemed to constitute an admission of the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be destroyed.

*See also Nos. 3550, 3551, 3553, 3565, 3570-3573.